REMARKS

1. Restriction is required under 35 U.S.C. §121 and §372. According to the office action, present claims must be restricted to one of the following five (5) groups:

Group I: claims 1-12 and 33;

Group II: claims 13-21;

Group III: claims 22-26;

Group IV: Claims 27-31

Group V: Claim 32

Applicants hereby confirm the election to prosecute the claims of Group I (i.e., 1-12 and 33).

4. The disclosure is objected to for certain informalities.

Applicants respectfully submit that the specification has been amended to correct the identified typographical error. Applicants therefore request this objection be withdrawn.

6. Claims 1-3 and 11 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,632,652 (referred to hereinafter as "Austin"). Specifically, the rejection provides that Austin teaches an apparatus (80) having a first planar member (26), a second planar member (88), wherein at least one of the first planar member and second planar members is transparent, at least three separators (62) disposed between the planar members, each separator individually having a height and the separators collectively having a mean height, and wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable. Applicants respectfully disagree with the characterization of Austin and the rejection based thereon.

The classic test for anticipation, under 35 U.S.C. §102, requires that every limitation in a claim must be present in a single source reference for that reference to "anticipate" the claimed invention.

Amended claim 1 of the present application recites as follows:

1. An apparatus for analyzing biologic fluid, comprising:

a first planar member;

a second planar member, wherein at least one of the first planar member and second planar member is transparent; and

at least three separators disposed between the planar members, each separator individually having a height and the separators collectively having a mean height, separating the planar members to form a chamber having a height extending between the planar members;

wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable when the first planar member and second planar member are drawn toward one another by capillary force from a biologic fluid quiescently residing within the chamber to cause the chamber height to be substantially equal to the mean height of the separators.

Austin Does Not Describe a Structure having a Planar Member that is Sufficiently Deformable Under Capillary Force to Cause the Chamber Height to be Substantially Equal to the Mean Height of the Separators

Austin describes a microstructure sorting devices as having a substrate 22 with a shallow receptacle 24 located on a side 26 of the substrate. (col. 2, lines 59-67) The receptacle includes a floor 28 bounded by walls 30, 31, and ends 32, 34. An array 38 of square-shaped obstacles 39 (or rectangular-shaped "bunkers" 62) extends outwardly from the floor 28. The obstacles / bunkers are disposed within the array in an "ordered and uniform pattern, staggered patterns, or any other predetermined and reproducible pattern." (Col. 4, lines 24-27) The passages formed between obstacles 39 are referred to as "pores 54" and are "constant and reproducible". (Col. 4, lines 28-49; see FIGS. 4 and 5 below)

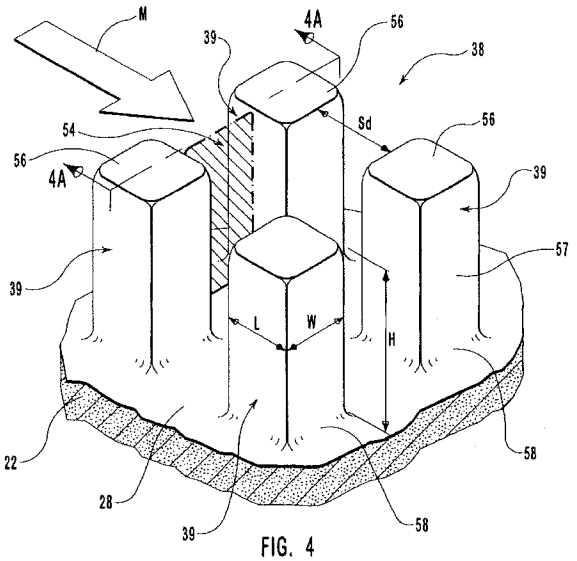


FIG. 4
(PRIOR ART)

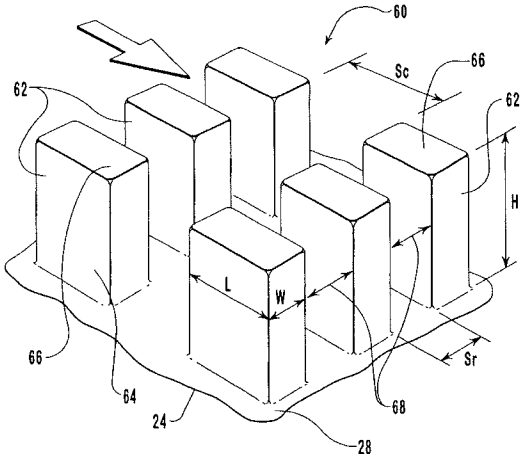


FIG. 5
(PRIOR ART)

The improved microstructure sorting device invention according to Austin is a device 80 wherein "one of the cover of the substrate is comprised of an elastomer." (Col. 7, lines 46-47) In one embodiment, the device 80 includes an elastomeric cover 88 that engages the top 66 of each bunker 62 in an array 86. According to Austin, the cover 88 is in contact with the top of the bunkers 62 to prevent migration of microstructures between the bunker tops 66 and the cover 88. (Col. 3, lines 48-50) The purpose of the elastomeric cover 88, according to Austin, is to permit the cover 88 to flex and be nondestructively removable from the substrate 22. (Col. 10, lines 4-15)

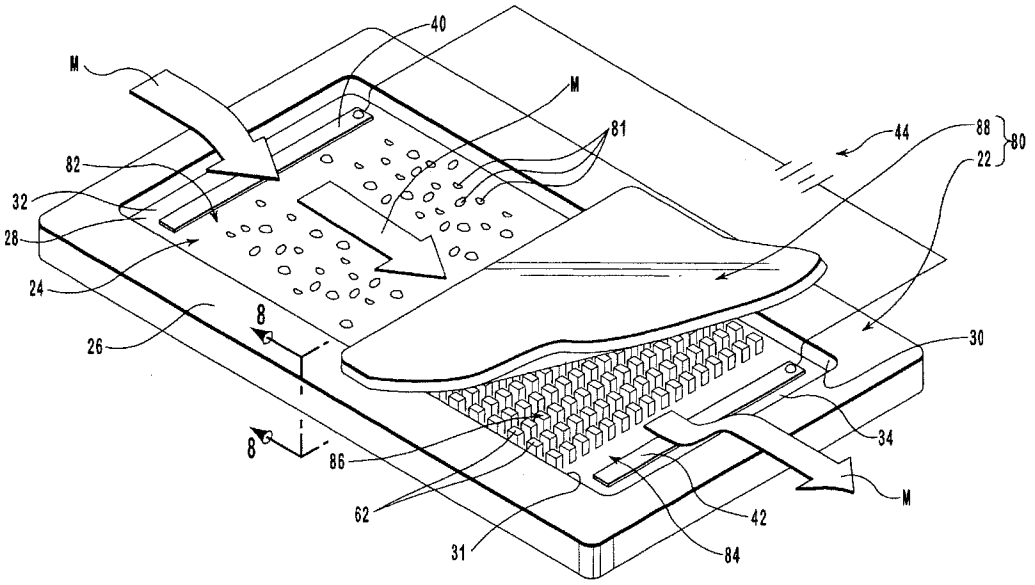


FIG. 7

Applicants respectfully submit that the disclosure by Austin of a sorting device having an elastomeric cover 88 that can be peeled back from the substrate 22 is not a disclosure of the claimed apparatus. Applicants respectfully direct the Examiner to paragraphs [0010] and [0013-0015] of the present application wherein the significance of the present apparatus is explained.

Even given that the cover 88 taught by Austin does touch the top 66 of each bunker 62, the structure of Austin is not the same as or equivalent to the claimed structure; e.g., there is no disclosure whatsoever in Austin that: 1) the cover deforms other than to be peeled back; 2) the cover is sufficiently deformable under capillary force from a biologic fluid quiescently residing within the chamber; or 3) the cover deforms in a manner that will to cause the chamber height to be substantially equal to the mean height of the separators throughout the chamber. As stated above, 35 U.S.C. §102 requires that every limitation in a claim must be present in a single source reference for that reference to "anticipate" the claimed invention. Since Austin does not disclose a structure as is recited in the claims (e.g., a planar member that is sufficiently deformable under capillary force from a biologic fluid quiescently residing within the chamber to cause the chamber height to be substantially equal to the mean height of the separators throughout the chamber), Austin cannot anticipate claims 1-3 and 11.

In addition, Austin actually teaches away from the apparatus recited in claims 1-3 and 11. As indicated above, there is no disclosure within Austin that the cover 88 deforms in any manner other than to peel back. Austin also does not contain any disclosure regarding the criticality of the uniformity of the height of the bunkers 62.[1] On the contrary, according to Austin, the "depth of receptacle 24 is *commensurate* with the size of the microstructures to be sorted" (Col. 3, lines 8-15; emphasis added), and "the height H of each bunker 62 *should* also be such as to allow the cells to pass through the bunkers 62 in *essentially* a single layer." (Col. 5, lines 32-33; emphasis added) There is no discussion within Austin regarding the criticality of the height of the bunkers 62 within the receptacle, individually or collectively, or the criticality of the chamber height. In fact, the terms "commensurate", "should", and "essentially" all teach away from the uniformity of the heights of the bunkers 62 being a critical dimension of the sorting device. Hence, a fair read of Austin without the benefit of hindsight is that Austin teaches bunkers having a height within a tolerance that enables them to be in contact with the cover. Such an apparatus teaches away from a device having a chamber height that is substantially equal to the mean height of the separators, and actually teaches one where the chamber height varies locally within the receptacle 24 as a function of the immediate bunker 62 heights. Consequently, the sorting device disclosed by Austin does not meet the claimed apparatus and actually teaches away.

Austin Does Not Describe a Separator that is Sufficiently Deformable Under Capillary Force to Cause the Chamber Height to be Substantially Equal to the Mean Height of the Separators

As indicated above, nothing within Austin discloses an apparatus having separators that are sufficiently deformable under capillary force to cause the chamber height to be substantially equal to the mean height of the separators.

In fact, rejections elsewhere within the office action indicate that "Austin does not specifically teach an apparatus wherein the separators are deformable relative to the first planar member and the second planar member." (Office Action p. 5) Consequently, it is

[1] Applicants respectfully disagree with the statement in the Office Action that provides: "the separators are projections of uniform height". Austin teaches that the *pattern* of the obstacles – not the heights - is uniform. (Col. 4, lines 23-26)

clear that Austin does not anticipate an embodiment of the invention wherein the separators are deformable relative to a first or second planar member.

In addition to the above, amended claims 1 and 33 provide that at least one of the first planar member, second planar member, or separators is sufficiently deformable when the first planar member and second planar member are drawn toward one another by capillary force from a biologic fluid quiescently residing within the chamber. There is no disclosure within Austin regarding capillary force acting on the planar member, and in particular no disclosure that capillary force drawing the planar members toward one another is sufficient to deform one of the planar members or separators. On the contrary, Austin discloses that: 1) a coverslip may be "bonded" to the substrate around the periphery of the sorting chamber 24, and to the "obstacles" 39 disposed within the chamber 24 (Col. 3, lines 48-55); 2) a coverslip can be attached by electrostatic attraction between the coverslip and obstacles 39 (Col. 6, lines 30-39); and 3) a coverslip may "spontaneously" seal with bunkers 62 in the array (Col. 12, lines 53-54) in a reversible and nondestructive manner. All of these embodiments are relative to bonds or seals created between the substrate and the coverslip. None of these embodiments disclose any interaction between the coverslip and the fluid within the receptacle. In fact, if capillary force was acting between the coverslip and receptacle of the sorting devices disclosed by Austin, there would be no need to bond or attach the coverslip and receptacle together.

9. Claims 4-6 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Austin. The rejection provides that separators "being made of an elastomer, would have greater deformability than [a] second planar member which is made of a rigid material... [and] the separators being very small projections... would have greater deformability". Applicants respectfully disagree with this characterization of Austin and the rejection based thereon.

Applicants direct the Examiner to the remarks above regarding claim 1, and for at least those reasons respectfully submit that the apparatus of claims 4-6 and 33 are not obvious in view of the disclosure of Austin.

In addition, applicants respectfully submit that there is no disclosure within Austin to support the proffered characterization of Austin. The ability of a substrate to

flex relative to a rigid coverslip does not equate to an analysis chamber having separators that are sufficiently deformable under capillary force to cause the chamber height to be substantially equal to the mean height of the separators.

Austin describes a microstructure sorting device having a substrate 22 with a shallow receptacle 24 with an array 38 of obstacles 39 or bunkers 62 extending outwardly from the floor 28. The obstacles / bunkers within the array are disposed in an "ordered and uniform pattern". (Col. 4, lines 24-27) The pores 54 formed between bunkers are "constant and reproducible". (Col. 4, lines 28-49) The fact that the pores 54 are "constant and reproducible" teaches away from deformable bunkers 62 which would necessarily deflect into the pores 54 and thereby make distance between adjacent bunkers 62 non-constant. As a result, the ability of the sorting device to properly operate would be compromised.

In addition, even if the obstacles 39 or bunkers 62 were deformable as the rejection suggests, the obstacles/bunkers would not dictate the height of the receptacle 24. As can be seen in FIG. 14, the rigid coverslip 36 clearly extends across the entire receptacle 24. As a result, the height of the interior chamber is a function of the tolerances of the flexible substrate 132, the receptacle 24, and the rigid coverslip 36. The allegedly deformable obstacles / bunkers would not dictate the height of the receptacle 24. In addition, as stated above, there is no teaching within Austin that capillary force would be adequate to deform the obstacles.

10. Claims 8 and 9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Austin in view of U.S. Patent No. 4,883,642 (referred to hereinafter as "Bisconte").

Claims 8 and 9 depend from claim 1. Applicants direct the Examiner to the comments above and respectfully submit for at least those reasons, the subject matter of claims 8 and 9 is not obvious in view of Austin and Bisconte.

13. Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Austin in view of U.S. Patent No. 6,551,554 (referred to hereinafter as "Vermeiden"). Specifically, the rejection provides that Austin teaches the use of a dye to allow for visualization of blood cells, and Vermeiden teaches the use of plastic beads. Applicants respectfully

disagree with the characterizations of the cited references and the rejection based thereon.

Claim 10 depends from claim 1. Applicants direct the Examiner to the comments above and respectfully submit for at least those reasons the subject matter of claim 10 is not obvious in view of Austin and Vermeiden.

In addition, Austin discloses the use of dyes to stain *cells* within a sample. Austin does not, however, teach or suggest the use of uniformly dyed slightly compressible plastic beads. Vermeiden discloses the use of particles 8. There is no disclosure within Vermeiden, however, regarding particles that are uniformly dyed or that are slightly compressible. On the contrary, Vermeiden discloses particles that may be made of plastic, or aluminum oxide, or glass. (Col. 4, lines 16-22) There is no disclosure of any of these materials as being slightly compressible, and aluminum oxide, glass, and many plastics are typically considered to be incompressible.

Vermeiden also discloses that "the material particles 8 having the largest dimensions will determine the depth of the counting compartment 1" (Col. 3, lines 33-35), and "the material particles 8 can of course contain smaller particles 8, but they do not determine the distance between the bottom plate 2 and the top plate 3." (Col. 4, lines 5-9) Clearly, from these passages it can be seen that the larger sized particles 8 do not compress within the chamber (even if they are plastic). In fact, the described apparatus suffers from the problem to which the present invention provides a solution. Hence, Vermeiden actually teaches away from the proposed combination.

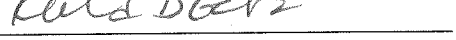
14. Claim 12 is rejected under 35 U.S.C. §103(a) as being unpatentable over Austin in view of U.S. Patent No. 7,179,423 (referred to hereinafter as "Böhm").

Claim 12 depends from claim 1. Applicants direct the Examiner to the comments above and respectfully submit for at least those reasons the subject matter of claim 12 is not obvious in view of Austin and Böhm.

New claims 34-36 have been added. Applicants respectfully submit that new claims 34-36 do not add any new matter and are believed to be patentable over the cited prior art for at least the reasons provided above. Applicants therefore request these claims be passed onto allowance.

Please charge the fee for a one month extension to deposit account no. 50-3381. In the event an additional fee is due, please also charge our Deposit Order Account No. 50-3381.

Respectfully submitted,



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